

U.S. Appn. No. 10/729,276
Amendment dated Sept. 6, 2005
Reply to Office Action of July 6, 2005

Confirmation No. 1586

REMARKS

Applicants respectfully request entry of the Amendment and reconsideration of the claims. Claim 1 has been amended. No new matter has been added through the amendment. Claims 1-6 are currently pending. Applicants respectfully request reconsideration and withdrawal of the objection to the Abstract and pending rejections under 35 U.S.C. §112, first paragraph, and 35 U.S.C. §103, and for obviousness-type double patenting.

Information Disclosure

The Examiner has not considered the Information Disclosure Statement filed March 5, 2004. Applicants submit with this amendment, initialed Form 1449s from the instant application's parent application, serial no. 09/820,199, now U.S. Patent No. 6,586,414. Under MPEP 609, Applicant is not required to re-submit a listing of information that has been considered by the Patent Office in a parent application when examining a divisional application filed under 37 C.F.R. § 1.53(b) unless the applicant desires the information to be printed on the patent. All of the art listed in the Form 1449 filed on March 5, 2004 was previously cited in parent application no. 09/820, 199, except for U.S. Patent No. 6,585,414 (which is the parent application) and U.S. Patent No. 6,339,085. Applicants hereby submit U.S. Patent No. 6,339,085 in a supplemental Form 1449 for the Examiner's consideration.

Co-pending and Related Applications

The Examiner has requested that the Applicants provide a complete list of co-pending and related applications. Co-pending and related U.S. applications are as follows:

60/192,774

09/820,199

10/254,197

Abstract

The Examiner objects to the abstract of the disclosure because the instant abstract recites compounds that are not present in the instant claims. Applicants has amended the abstract accordingly.

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Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejects claims 1-6 under 35 U.S.C. §112, first paragraph, for an alleged lack of enablement. Specifically, the Examiner acknowledges that there is support for treatment of cerebral ischemia or ischemic stroke using pyridoxal-5'-phosphate, but asserts that the specification does not reasonably provide enablement for the treatment of cerebral ischemia, cerebral hemorrhage, ischemic stroke or hemorrhagic stroke comprising administering pyridoxal-5'-phosphate, pyridoxal, pyridoxine, or pyridoxamine.

Solely in an effort to expedite prosecution, and not to accede to the point, Applicants have amended the claims of the present application to limit the scope to treatment of cerebral ischemia or ischemic stroke using pyridoxal-5'-phosphate. Applicants have done so without prejudice and maintain their rights to file divisional applications for the other compounds and disease states.

Rejections Under 35 U.S.C. §103

Claims 1-6 are rejected under 35 U.S.C. §103(a) for alleged obviousness. The Examiner asserts that claims 1-6 are unpatentable over Skochii et al., *Likars'ka sprava/Ministerstvo okhorony zdorov'ia Ukrainy*, (Sept.-Dec., 1994) (9-12)109-11 (abstract). Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness, three criteria must be met--a suggestion or motivation to combine references, a reasonable expectation of success, and the prior art reference teaches or suggests all the claim limitations. MPEP §2143; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness since Skochii et al. do not provide a reasonable expectation of success that pyridoxal-5'-phosphate alone would be successful in treating cerebral ischemia and ischemic stroke.

Skochii et al. teach the administration of a regimen of tocopherol acetate (vitamin E), ascorbic acid (vitamin C), pyridoxal phosphate, and glutamic acid. Skochii et al. do not teach that any of the individual components of the regimen will be successful in treating cerebral ischemia and ischemic stroke. According to the Skochii et al., it is this cocktail that produces the reduction in LPO concentration. At page 2, 3rd full paragraph ("In 12 patients..."), Skochii et al.

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describe the role of each of the different components. If each component of the regimen has a role, then there is no reasonable expectation of success that the individual component of pyridoxal-5'-phosphate would treat cerebral ischemia and ischemic stroke. As such, Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

Obviousness-Type Double Patenting Rejections

The Examiner has raised an obviousness-type double patenting objection in relation to claims 11-18 and 21-28 of copending Application No. 10/411,552. The Examiner has also raised a provisional obviousness-type double patenting objection in relation to claims 1 and 20 of copending Application No. 10/639,955. While not acquiescing to the rejections and in order to expedite prosecution, Applicants submit a terminal disclaimer to obviate the obviousness-type double patenting rejections. Applicants respectfully request removal of the obviousness-type double patenting rejections.

CONCLUSION

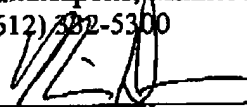
In view of the above amendments and remarks, Applicants respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date: September 6, 2005





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